



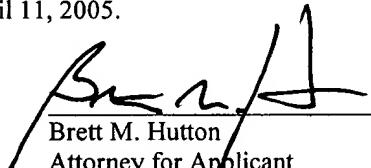
Applicant: Wisniewski et al.
Serial No.: 08/895,936
Filed: July 17, 1997
Docket No. 2035.706

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Wisniewski et al. **Group Art Unit:** 3753
Serial No.: 08/895,936 **Examiner:** John K. Ford
Filed: July 17, 2001 **Appeal No.:**
Title: FREEZING AND THAWING VESSEL WITH THERMAL BRIDGE FORMED
BETWEEN HEAT EXCHANGE MEMBERS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 11, 2005.



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Date of Signature: April 11, 2005

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**REPLY TO EXAMINER'S ANSWER BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Dear Sir:

This is a reply under 37 CFR § 1.193 from an Examiner's Answer dated February 9, 2005. Therefore, this Reply Brief is timely filed within two months, i.e., by April 12, 2005 under 37 C.F.R. §1.7(a).

ARGUMENT

This paper relates to the Grounds Of Rejection and Response to Argument sections of the Examiner's Answer, dated February 9, 2005, which is incorporated herein by reference. The points raised in the Examiner's Answer are addressed below.

1. **“Biopharmaceutical Product”**

Appellant acknowledges the Examiner's withdrawal of the rejection directed to the term “biopharmaceutical product.” However, Appellant respectfully notes that the explanation on page 7 of its Appeal Brief is a repetition of the same argument provided on pages 11 and 12 in an Amendment and Response, dated January 7, 2002. Therefore, the Examiner's statement that “Appellant has explained clearly [why buffers should be included in the definition of “biopharmaceutical products”] for the first time” is misplaced.

The Examiner wants the Board to completely ignore five declarations from persons of ordinary skill in the art in the field concerning the processing concerns of biopharmaceutical products. The Examiner has in the past characterized this evidence as “self-serving at its core”, without providing any evidence of his own to contradict statements made by those skilled in the art. Aside from the Examiner's own self-serving statements, these declarations remain uncontested. In fact, the Examiner repeatedly ignored Appellant's request during prosecution that the Office show, in contradiction to the declarations submitted by Appellant, that products such as orange juice, milk and comestibles¹ require uniform freezing at a rapid pace to prevent damage, as recognized in Appellant's specification relative to the processing of biopharmaceutical products. Instead, the Examiner repeatedly asserted his own personal, unsupported opinions based his masters degree in engineering on this issue in the Office Actions. Even in his Answer, the Examiner asserted “it is well known in the heat transfer art that scientists

¹ The Examiner's suggestion that Appellants produced art for consideration during prosecution related to the freezing of food products because they considered them to be “related” is improper. The modification of the language of 37 CFR 1.56 in 1992 emphasized that there is a duty of candor and good faith that is broader than the duty to disclose material information. MPEP 2001.04. In fact, the Patent Office continued to expect that applicants would continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. Id. Clearly, the submission of any prior art reference during prosecution for consideration by the Office is not an admission by an applicant that the references are material.

routinely make heat transfer measurements in one material that can be extrapolated to other materials by known correlations, such as Reynolds number, Prandtl number and Nusselt number." However, he provides no support for this alleged "well known" fact. More importantly, he provides no explanation of how this relates to the problem addressed by the present invention and supported by the declarations of those skilled in the art for the need to preserve biopharmaceutical products to prevent damage as compared to other non-biopharmaceutical products, such as orange juice, milk and comestibles, not to mention how these products fall within the approved meaning of the term "biopharmaceutical products". Moreover, he makes a number of unsupported statements in his Answer that "much of [the] prior art related to freezing of food products appears in the Appendices of the 1996 Wisniewski and Wu prior art – which isn't true, and that "much of the prior art relied upon in the rejection discusses the problems of attaining uniform freezing of liquid food products" – which also is untrue.

2. The Examiner Offers No Evidence That A Thermal Bridge Inherently Forms In The Device Disclosed in the 1992 Wisniewski and Wu Article or As A Result Of Any Combination of the Other Cited References

The Examiner states that the Wisniewski and Wu article "inherently forms a thermal bridge". However, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In the instant case, the Examiner merely offers his own speculation to contradict the declarations submitted by a person familiar with the present invention and the primary reference asserted by the Office. He also failed to provide any objective evidence or cogent technical reasoning to support his conclusion of inherency that a thermal bridge forms in the Genentech device or a combination of any of the cited references. The Examiner simply states that a "thermal bridge of ice" will inherently form between the tip of the heat transfer fins and the interior of the container because they "are the closest points to one another and both are actively cooled by circulating cooled silicon oil." (See Final Office Action, page 17). The Examiner references United States Patent No. 983,466 to

Voorhees, which discloses that if elements are “close together the ice surrounding these elements will coalesce into a single cake; and after this has occurred freezing will go on from the surface of the combination of cake so formed.” Id. However, this does not describe a thermal transfer bridge (i.e. downward temperature gradient from the structure to the interior surface of the container).

Appellant has asserted throughout prosecution that the 1992 Wisniewski and Wu article accurately depicts the prior art device (“Genentech device”) to the best of Mr. Wisniewski’s memory. The applicants disclosed this article during prosecution and, in an effort to assist the Examiner understand the same, provided declarations from Mr. Wisniewski, who was familiar with the structure and operation of the Genentech device, to offer the best explanation of the Genentech device. Mr. Wisniewski stated that the distance between the fin tip and the interior wall of the Genentech device “was greater than 4 inches” based on his memory. The specification, of the instant application, teaches that the optimum gap for the formation of a thermal bridge is “less than 2 inches, preferably less than 1 inch, more preferably less than $\frac{1}{2}$ inch, even more preferably less than $\frac{1}{4}$ inch, and most preferably less than $\frac{1}{8}$ inch”, which was See Specification, page 5. The specification supports the fact that Appellant conducted a simulation in arriving at Figure 3b that depicts the thermal bridge. (See Specification pages 10-11).

Throughout his brief, the Examiner attempts to discredit the conclusions and schematic depictions offered by Mr. Wisniewski and the credibility of Mr. Wisniewski himself, while ignoring and/or diminishing his knowledge of and experience with the present invention and the Genentech device. Despite Mr. Wisniewski’s knowledge and experience with the devices, the Examiner unilaterally reduces his statements and schematics to “guesses.” In fact, it is apparent that nothing short of actual experiments and/or computer analysis on all the prior art, including devices not in the possession or control of Appellant, would satisfy the Examiner. In fact, the Examiner goes as far as requiring Appellant contact a competitor/customer to ask for the dimensions of their device. (See Examiner’s Answer, page 18). Moreover, contrary to the Examiner’s statement in his answer that he never made any “requirement” for Appellant to test anything, Appellant direct the Board to page 11 of the Final Office Action in which the Examiner states that he has “**repeatedly asked** Mr. Wisniewski **to test this prior art**, or a

reasonable facsimile of it, using temperature transducers" (emphasis added), and on page 16 in which the Examiner questions why Appellant does not use its sophisticated modeling and equipment to perform experiments on its own device and the prior art.

In contradicting Mr. Wisniewski's declarations, the Examiner relies on his own characterizations and predictions of freezing of different types of products occurring in different types of devices using different freezing principles². However these characterizations and predictions are nothing more than mere speculation, unqualified assumptions and unsupported by evidentiary proof, despite Appellant's repeated request during prosecution for the same from the Examiner. The Examiner also attempts to manufacture admissions and concessions in his favor by twisting certain statements around and ignoring conflicting arguments and support offered by Appellant throughout prosecution. The fact that the Examiner is "very suspicious" of Mr. Wisniewski and his declaration is not grounds to support the refusal to issue the instant application.

3. Alleged Improper Combinations of References

As set forth in the Brief of Appellant, there is no motivation or suggestion to combine the cited references because each reference freezes products by completely different ways using completely different freezing principles. For example, the 1992 Wisniewski and Wu publication teaches cooling the outside and inside of the cylinder, the 1986 Kalhori and Ramadyani article teaches heating the medium from the outside of the cylinder while the structure within was cooling it and the other cited references disclose a completely different method of freezing from the previous two references, as fully explained in Appellant's initial Appeal Brief.

The Examiner over simplifies the motivation to combine references asserted in the Office Action and ignores the problems in processing biopharmaceutical materials recognized by Applicants in the specification (see page 6 of the Specification), which was supported by declarations of four people of ordinary skill in the art. Instead, the Examiner combines the cited references on the sole basis that the devices disclosed therein freeze products – nothing more. However, the Examiner has not and cannot point to anything in the references that the

² Appellant's position on the different freezing principles used by the cited references is explained in more detail in its initial Appeal Brief.

combination of the 1986 Kalhori and Ramadhyani and the 1992 Wisniewski and Wu reference or any of the other cited references will result in the formation of a thermal bridge as required by the claims of the instant application. Simply because one reference is cited in the appendix of another reference is insufficient, alone, to support the Examiner's position. In reality, the Examiner improperly combines the cited references based on an "obvious to try" basis, without pointing to any suggestion, motivation or disclosure in the references themselves to support such a combination.

The Examiner merely concludes that all of the cited references, individually and taken in the aggregate, teach reasons for extending the fins in the 1992 Wisniewski and Wu article to a point close to the jacket wall. In support of this conclusion, the Examiner improperly refers to Appellant's own application as a teaching guide to support the conclusion that very large fins work extremely well. (See Examiner's Answer, page 15). In his answer, the Examiner alleges, with no support, that "[p]araffin is [sic] an excellent substance to do heat transfer experiments on because of its well understood physical properties", and therefore the 1986 Kalhori and Ramadhyani is "not an irrelevant reference to combine" with the 1992 Wisniewski and Wu article. However, the Examiner completely ignores his burden and the requirement under an obviousness rejection. The Examiner fails to reference any motivation, suggestion or disclosure in any of the references, including the 1986 Kalhori and Ramadhyani article, that supports the extension of the fins in the device disclosed in the 1992 Wisniewski and Wu article to result in the formation of a thermal transfer bridge that will address the problems recognized by Appellant in processing biopharmaceutical products.

One of the reasons the Examiner attempts to rely on for the extension of the fins is to improve the division of the tank into compartments. However, the Examiner fails to explain the motivation in extending the fins of the Genentech device when the 1992 Wisniewski and Wu article already explains that the heat transfer fins are configured to divide the tank volume into compartments (see page 136) and the 1986 Kalhori and Ramadhyani article fails to even address this issue. Another reason the Examiner supports his reasoning to increase the size of the fins is to increase the rate of heat transfer. However, this reason merely restates the conclusion reached by Appellant's invention. The Examiner fails to point to anything in any of the references that increasing the size of fins into closer proximity to an interior wall that is cooled, not heated like

the device in the 1986 Kalhori and Ramadhyani article, would result in an increase the rate of heat transfer in the Genentech device.

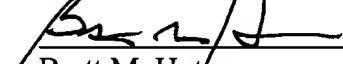
Appellant never admitted in the Appeal Brief that no human being can accurately predict the temperature profiles of the devices disclosed in the references. Instead, Appellant argues that, if the Examiner truly believes that a computer is required to predict temperature profiles and bases his rejection on this conclusion, how can he support a rejection based on an obvious combination of the references. Moreover, along the same lines, Appellant questions how the Examiner can make a number of unsupported statements throughout his answer that a thermal bridge "must form" and that a downward gradient "will occur" if you "wait long enough." (See e.g. Examiner's Answer, page 8-11). These statements are not supported by anything but the Examiner's own unqualified opinion and contradict the statements asserted by Mr. Wisniewski in declaration form, which remain uncontested by any fact and/or technical reasoning.

CONCLUSION

For the reasons set forth above and in the initial Brief of Appellants, reversal of the rejections and allowance of this application are respectfully requested.

Dated: April 11, 2005

Respectfully submitted,


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